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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,574	07/28/2005	Shizuo Shiozaki	00005.001262	4499

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
04/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,574	SHIOZAKI ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 01/11/2008. Claims 1 and 7 are pending in the application, with claims 2-6 and 8-9 having being cancelled. Accordingly, claims 1 and 7 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Examiner further acknowledges amendment of claims 1 and 7 and cancellation of claims 2-6 and 8-9 and consequently the rejections under 35 U.S. C. 101 and 112, second paragraph has been withdrawn.

Applicant's argument with respect to Kase as being unavailable as a reference under 35 U.S. C. 102 (e) has been considered and is found persuasive. Consequently, the 102 (e) rejection is withdrawn.

In view of applicant's amendment, the following new obviousness double patenting, 102 (b) and 103 (a) Non-Final rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-14 of copending Application No. 10/579829 (hereinafter Kase US Patent Application No. '829). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method

of treating higher brain dysfunction. The claimed invention and co-pending application Kase '829 are rendered obvious over another as the claimed invention teaches a subgenus of a method of treating two specific higher brain dysfunction such as Tic/Tourette and attention deficit hyperactivity disorder using a particular xanthine derivative whereas Kase '829 teaches a broad genus of higher brain dysfunction with a broad genus of xanthine derivatives. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/579829.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/488623 (hereinafter Shimida US Patent Application No. '623). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating attention deficit hyperactivity disorder. The claimed invention and co-pending application Shimida '623 are rendered obvious over another as the claimed invention teaches a method of treating attention deficit hyperactivity disorder utilizing a subgenus of xanthine derivatives whereas Shimida '623 teaches a method of treating attention deficit hyperactivity disorder utilizing a broad genus of xanthine derivatives. Thus, the aforementioned claims of the instant application are substantially overlapping in scope

as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/488623.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 7 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51, 53-55, and 57 of copending Application No. 10/353240 (hereinafter Kase US Patent Application No. '829). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating movement disorders including dyskinesia using A2a receptor antagonists. The claimed invention and co-pending application Kase '240 are rendered obvious over another as the claimed invention teaches a subgenus of a method of treating movement disorders such as Tic/Tourette which is characterized by dyskinesia using a particular A2a receptor antagonist whereas Kase '240 teaches a broad genus dyskinesia with a broad genus of A2a receptors antagonists. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/353240.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Shimada et al. (WO 99/12546).

WO 99/12546 is the PCT counterpart to U.S. Patent 6,727,259 B2. WO 99/12546 is prior art under U.S.C. 102 (b) as a result of its March 18, 1999 publication date. U. S. Patent 6,727,259 B2 is the national stage application of WO 99/12546. Because WO 99/12546 and U.S.Patent 6,727,259 B2 appear to have identical disclosures, the U.S. Patent is being used as a translation of WO 99/12546 PCT. While any reference hereinafter to column and line numbers will be based upon the U.S. patent disclosure, such reference should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Specifically, Shimada et al. discloses therapeutic agents for the treatment of neurodegenerative disorders with xanthine derivatives (see abstract and col. 9, claim 2). Importantly, Shimada et al. discloses the use of preferred compounds (E)-8-(3,4,-dimethoxystyryl)-1,3-diethyl-7-methylxanthine in its method (see table 1, compound, col.

3, lines 55-66 and col. 4, lines 34-35). Furthermore, Shimada et al. discloses that the aforementioned compound or its pharmaceutical salts to be useful in the treatment of neurodegenerative disorders such as attention deficit hyperactivity disorder (instant claim 1; col. 6, lines 41-43 and 47-49).

Accordingly, the teachings of Shimada et al. anticipate claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Brown et al. (IDrugs, May 2002, pg. 454-468, previously submitted by applicant and filed on an IDS 1449) in view of Leckman et al. (Neuron, Nov. 2000, Vol. 28, pgs 349-354).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Brown et al. teaches that certain treatments can result in uncontrolled involuntary movements (termed dyskinesia) (see pg. 454, abstract). Brown et al. further teaches that that the mechanism being affected by such disruptive treatments involve abnormalities in neurotransmission in the basal ganglia leading to an imbalance between two striatal output pathways and adenosine A2a receptors (see pg. 454, Mechanisms Section). Brown et al. further teaches that novel treatments such as the use of Adenosine A2a receptor antagonists such as KW-6002 (i.e. E)-8-(3,4,-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) can be used to combat these symptoms given that the A2a receptors are localized in striatum and can therefore oppose these effects (see pg. 460, Adenosine A2a receptor section). Moreover, Brown et al. teaches that mRNA levels of A2a receptors were found to be elevated in dyskinetic non-human primates and that mice with a mutation in A2a receptor did not exhibit any uncontrolled movements suggesting the involvement of A2a receptor antagonists in uncontrolled involuntary movements (see pg. 460, Adenosine A2a receptor section).

Brown et al. does not specifically teach a method of treating Tic/Tourette's disorder or a method of treating attention deficit hyperactivity disorder using the aforementioned compound.

Leckman et al. teaches that Tourette syndrome is characterized by motor and phonic tics that wax and wane in severity and is a movement disorder (see pg. 349, left col. paragraph 2). Leckman et al. further teaches that mechanism that leads to tic production may involve the basal ganglia, its cortico-cortical connections, prefrontal cortex and caudate nucleus (see pg. 350, right col. paragraph 3 and pg. 351, left col. paragraph 1). Importantly, Leckman et al. teaches that Tourette patients may also suffer from other co-morbidities such as attention deficit disorder and that treatment of co-morbid disease (i.e. attention deficit disorder) will often diminish tic severity (see pg. 349, right col. paragraph 4, and pg. 353, left col. paragraph 1). This suggests that both Tic/Tourette disorder and attention deficit disorder share the same mechanistic pathway of action.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Brown et al. to treat Tourette syndrome since Brown et al. teaches that uncontrolled involuntary movements involves the basal ganglia area along with its neural loops and since Leckman teaches that Tourette is a movement disorder which involves the basal ganglia. Similarly, one of ordinary skill would have found it obvious to treat attention deficit hyperactivity disorder with the method of Brown et al. given that Leckman et al. teaches that treatment of attention

deficit hyperactivity disorder lessens the severity of Tourette and consequently this suggests a common mechanistic pathway in the etiology of both disorders. Given that Brown et al. teaches a method of treating uncontrolled involuntary movements involving the basal ganglia area, and Leckman et al. discloses that Tourette syndrome is a movement disorder which involves the basal ganglia and that treatment of attention deficit hyperactivity disorder would lessen the severity of Tourette, one of ordinary skill would have been motivated to utilize the method of Brown et al. to treat attention deficit disorder or Tic/Tourette syndrome in light of the disclosure of Leckman et al. with the expectation of providing a reasonable method that is efficacious in lessening the severity of Tourette syndrome and efficacious in treating attention deficit hyperactivity disorder and Tourette syndrome.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

03/27/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617